REMARKS

Claims 1-7 and 12-37 are pending in the application, of which claims 12-32 and 34 have been withdrawn from examination. Claims 1 and 34 are amended, claims 5-7 and 37 are canceled, and new claim 38 is added herein. Reconsideration of the present application is respectfully requested.

Claims 1-4, 7 and 36 have been rejected under 35 U.S.C. 103(a) over U.S. Patent No. 6,264,625 to Rubenstein. The Office Action has recognized that Rubenstein does not disclose that the pump is situated in a housing having an anti-infective coating but the Examiner has reasoned that such limitation is obvious in view of Rubenstein's teaching of antibodies coated on a container identified by reference number 52 in Rubenstein's disclosure.

Applicant notes that Rubenstein teaches the use of antibodies in the embodiment depicted in Rubenstein's FIG. 9, reproduced below:

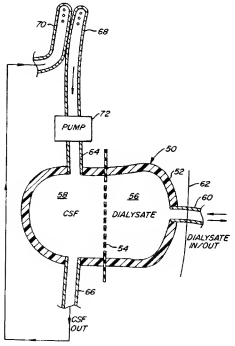

FIG. 9

As described in detail at col. 9, lines 27-58 of Rubenstein, in this particular embodiment, cerebro-spinal fluid (CSF) is purified with a dialysis process based on drawing the CSF into an end portion 68 of the shunt system while controlling flow with a pump 72. The CSF is then

forced through a conduit 64 and enters dialysis apparatus 50, which includes a fluid chamber 58, a microporous membrane 54, and a dialysate chamber 56. Toxic or putative chemicals in the CSF move from fluid chamber 58 into dialysate chamber 56 by diffusing through microporous membrane 54 due to the gradient in toxic chemical concentration between the CSF in fluid chamber 58 and the dialysate in dialysate chamber 56.

The inner wall of dialysate chamber 56 may be coated with antibodies specific to certain toxins present in the CSF so to capture those toxic in the dialysate and draw them out of solution, keeping high the concentration gradient between CSF and dialysate. Alternatively, the antibodies may be bound to beads, strands or other structures which may be periodically introduced into and retrieved from the dialysate chamber through dialysate port 60.

Rubenstein provides that predetermined toxins may be extracted from a shunted fluid though a dialysis system, and that the efficiency of the dialysis process may be increased by drawing out of the dialysate solution certain undesired chemicals by the addition of specific antibodies to the dialysate chamber. A "toxin" is a poisonous substance produced by living cells or organisms that is active at very low concentrations and is not the micro-organism itself.

In *Ex parte So and Thomas*, BPAI 2007-3967 (Board of Patent Appeals and Interferences, January 4, 2008), it was held that the references cited in an obviousness rejection must motivate an artisan to select a particular ingredient and apply it as taught by the patent applicant. Applicant submits that a person skilled in the art at the time of Applicant's invention, by reading Rubenstein, would not have been led to coat the surface of the pump with anti-infective agents to prevent the spreading of infections, because Rubenstein discloses a pump but applies no anti-infective coatings on that pump and uses the coating as a trapping medium for predetermined toxins within a dialysis system rather than as an anti-infective medium.

U.S. Patent No. 5,980,478 to Gorsuch et al. (cited in the Office Action) confirms the difference between a toxin-removing coating noted herein and an anti-infective coating by drawing a difference between toxin-removing coatings used in dialysis systems and anti-infective coatings. See Gorsuch, col. 2, line 22 – col. 3, line 6.

Applicant further submits that Applicant's invention should not be deemed obvious only because it resolves the long-felt need to prevent the propagation of infections in a shunting

system by disclosing an elegantly simple solution. Scientific and trade literature published after the publication of Rubenstein and of Applicant's invention emphasize the need to reduce bacterial infections caused by or derived from shunt systems. Four scientific publications and one educational publication expressing that need are enclosed herein. Therefore, there was a long-felt need at the time of Applicant's invention for a shunting system that prevents the propagation of infections, which was resolved by Applicant's invention.

In view of the foregoing, Applicant submits that Rubenstein fails to teach or render obvious an implantable fluid management system that includes one or more anti-infective coatings disposed on a surface of the pump, as recited in Applicant's claim 1. Therefore, the rejection of claim 1 and of the claims depending therefrom as obvious in view of Rubenstein is respectfully traversed.

It is believed that claim 1 is also patentably distinguishable over the combination of Rubenstein with Gorsuch, both for the same reasons as claim 1, and also because Gorsuch does not teach or suggest coating a pump but rather coating a catheter. No reason is apparent from Gorsuch or any of the other cited prior art why a person skilled in the art at the time of Applicant's invention would have been motivated to coat the pump rather than a catheter by reading Rubenstein and Gorsuch.

With regard to the rejection of claims 5-6 over the combination of Rubenstein with U.S. Patent No. 5,947,911 to Wong et al., this rejection is now moot because claims 5-6 have been canceled. It is submitted that new claim 38 is patentable over the combination of Rubenstein and Wong for the same reasons as for claim 1, and because the combination of these references does not teach or suggest disposing a first sensor at the inflow port of the system and a second sensor at the outflow port of the system. It is further submitted that new claim 38 is fully supported in the specification, for example at paragraph [0059].

With regard to the rejection of claim 33, it is submitted that claim 33 is patentable for the same reasons as claim 1. Additionally, Applicant could find no teaching in U.S. Patent No. 6,193,684 to Burbank that the housing of a pump comprises anchors opposing rotational forces generated by the pump, such as barbed insertion pins, a screw threading defined on an outside surface of the pump, staples, adhesive compounds, one or more pins designed to be inserted into the abdominal wall, and combinations thereof. Burbank teaches at col. 5, lines 34-37 that a

subcutaneous catheter may be held in place with adhesives, staples, sutures, or other attachment techniques known in the art. However, Burbank does not teach or suggest that rotational forces of an implanted pump may be opposed as described and claimed by Applicant.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is now in condition for allowance. A notice to that effect is respectfully requested.

Dated: June 23, 2008

Respectfully submitted,

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SHUNTS FOR HYDROCEPHALUS

WHEN SHOULD I CONSULT MY PHYSICIAN?

Even if the risk of complication is low, the patient or his family need to know that certain complications may arise after the operation.

The main complications of shunts are obstruction, infection and overdrainage. These complications require prompt attention by the patient's physician.

Obstruction

The most common complication is obstruction, which can occur at any point of a ventriculo-atrial or ventriculo-peritoneal shunt.

The ventricular catheter can be obstructed by a blood clot, cerebral tissue, or even tumor cells.

The tip of the ventricular catheter can also become embedded in the choroid plexus or ventricular wall, either directly or following collapse of the walls due to overdrainage.

The cardiac catheter can be colonized by thrombus, while the development of clot around the catheter can lead to pulmonary embolism.

The peritoneal catheter can be obstructed by peritoneum or loops of intestine.

Loss of patency of a shunt may also be due to obstruction by fragments of cerebral tissue or biological deposits (protein deposits, etc.).

Obstruction of the shunt leads to loss of control of hydrocephalus, rapidly reflected by recurrence of the symptoms and signs of raised intracranial pressure.

These symptoms and signs vary from one patient another and over time.

In infants and young children, the symptoms may consist of an abnormal increase in the size of the skull, swelling of the fontanelles, dilatation of scalp veins, vomiting, irritability with loss of attention, downward displacement of gaze and sometimes convulsions.

In older children and adults, the raised intracranial pressure due to hydrocephalus is responsible for headaches, vomiting, visual disturbances, diplopia, drowsiness, slowed movements, gait disorders, psychomotor retardation, possibly causing total disability.

Shunt obstruction can also lead to CSF leakage around the catheter and subcutaneous collection.

If obstruction is confirmed, the shunt should be removed.

Infection

Chronic shunt dysfunction can lead to leaking of CSF along the shunt, increasing the risk of infection.

Local or systemic infection is another possible complication of CSF shunt systems. It is generally secondary to colonization of the shunt by cutaneous bacteria. However, as for

any foreign body, the shunt can be colonized by any local or systemic infection. This infection may present in the form of erythema, oedema and cutaneous erosion along the course of the shunt.

Prolonged, unexplained fever may also be due to infection of the shunt system.

Septicemia, in a context of deterioration of the general state, may arise from shunt infection.

The shunt system should be removed and specific treatment should be introduced in the case of infection.

Overdrainage

Overdrainage can lead to collapse of the ventricles (slit ventricles) and the development of subdural haematoma.

In children, depression of the fontanelles, overlapping of skull bones, or even acute craniostenosis or the development of communicating hydrocephalus into obstructive hydrocephalus as a result of stenosis of the aqueduct of Sylvius may occur.

In addition to various symptoms such as vomiting, auditory or visual disorders, drowsiness, adults may also present with headaches occurring in the upright position and resolving in the supine position.

Depending on the clinical and CT findings, the neurosurgeon can correct the symptoms and ventricular size by varying the operating pressure of the Sophy® Adjustable Pressure valve. However, immediate drainage of a subdural haematoma may be indicated.

Others

Failure of a shunt system may also be due to disconnection of its various components.

The ventricular catheter can migrate inside a lateral ventricle. The peritoneal catheter can migrate in the peritoneal cavity in response to intestinal peristalsis and an atrial catheter can migrate in the right side of the heart as a result of blood flow.

An abdominal viscus may also be perforated or occluded by the peritoneal catheter.

Bodily growth may progressively lead to expulsion of the catheters from their site of insertion.

These disorders require immediate resitting of the shunt.

Cases of skin necrosis over the implantation site have been reported.

In the case of implantation on the skull, vibrations due to CSF flow may be perceived.

Cases of silicone allergy have been described.

Cases of epilepsy after ventricular shunting procedures has been reported.

Cases of axial rotation of the valve by the patient have been reported, while implanted on the chest. Such rotation induces reverse lecture of the pressures and a risk of catheter obstruction.

The ruby ball can be maintained in off centering position on its seat by protein deposit or cells accumulation. The consequences of such situation can be:

- A lack of flow regulation of the valve inducing a risk of overdrainage.
- An impaired antireflux function.

Rotor blockage by protein deposit or cells accumulation can make adjustment impossible with the magnet.

Warnings & Cautions

- The pressure settings should always be checked in case of shock on the implantation site.
- Changing pressure settings must only be performed by a neurosurgeon.
- Patient must be advised that carrying his Patient Identification Card is important and necessary for the follow-up of the clinical conditions.
- Patients undergoing MRI exposure should be advised that they might feel a small yet harmless effect due to MRI.
- The pressure settings should always be checked before and after MRI exposure, or after strong magnetic field exposure.
- Patient must be advised that in the case of implantation on the skull vibrations due to CSF flow may be perceived.
- Patients with implanted valve systems must be kept under close observation for symptoms of shunt failure.

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Journal of Clinical Neuroscience
Volume 14, Issue 6, June 2007, Pages 526-531

doi:10.1016/j.jocn.2006.11.003 Cite or Link Using DOI

Clinical study

Reduction in shunt infection using antibiotic impregnated CSF shunt catheters: An Australian prospective study

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Received 25 September 2006; accepted 25 November 2006. Available online 10 April 2007.

Abstract

Antibiotic impregnated shunt catheters have emerged as a promising tool against the continuing challenge of shunt infection. We present our prospective evaluation of the efficacy of antibiotic (rifampicin and clindamycin) impregnated cerebrospinal fluid (CSF) shunt catheters (AIC) in a mixed paediatric and adult Australian population. We have prospectively evaluated all the cerebrospinal fluid shunt procedures carried out in our institution over a 3-year period since July 2002, after the introduction of AIC in our practice. Patient demographics, indication for shunt procedure, risk factors for infection, shunt infections and other relevant factors were documented. The data has been compared with similar data collected over the previous 7 years of our experience with non-antibiotic impregnated catheters for CSF shunt procedures. Pearson's chi-square and Fisher's exact tests are used for statistical evaluation. From July 2002 to June 2005, 243 shunt procedures were carried out using AICs in 178 patients. There were three shunt infections (1.2%). Rigorous retrospective evaluation of shunt procedures over the preceding 7 years revealed 36 infections in 551 shunt procedures (6.5%). This reduction in the infection rate was statistically significant ($p = 0.0015$ on Pearson's chi-square test and $p = 0.000529$ on Fisher's exact test). We also report that the introduction of ceftriaxone prophylaxis during this period was associated with a reduction in Gram-negative shunt infection, but no effect on overall infection rate. We report rifampicin and clindamycin impregnated CSF shunt catheters significantly reduce the rate of shunt infection in Australian clinical practice. This data and the literature support the routine usage of AIC for all CSF shunt procedures.

Keywords: CSF shunt infection; Antibiotic impregnated CSF shunt catheters; Rifampicin; Clindamycin; Ceftriaone

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Journal of Clinical Neuroscience
Volume 14, Issue 6, June 2007, Pages 526-531

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Journal Article

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Received: 7 November 2006 **Published online:** 7 February 2007

Abstract

Objective Shunt infection is a common and serious complication of cerebrospinal fluid (CSF) shunting most commonly caused by skin flora contamination at surgery. Recent studies indicate that the use of antibiotic-impregnated (AI) shunt systems may reduce the risk of postoperative shunt infections. We evaluated the incidence of shunt infections associated with the use of AI shunt catheters and compared it with the incidence associated with standard non-AI catheters.

Materials and methods All shunt procedures performed by one surgeon using AI catheters were reviewed. An equal number of consecutive shunt procedures performed by the same surgeon using non-AI catheters were reviewed from the period immediately before the introduction of the AI system. Patients with <9 months of follow-up were excluded; all shunt infections and shunt-related complications were recorded. The proportions of infected shunts in the AI and control groups were compared using a χ^2 analysis.

Conclusion We reviewed 160 shunt procedures (80 per group). The infection rate was 5.0% among patients with AI catheters compared with 8.8% in the control group ($P = 0.534$, Fischer's exact). The average time to infection was similar between the two groups. Among the AI group, the shunt infection rate did not differ between ventricular catheter, distal catheter revisions, and revisions of ventricular and peritoneal tubing. In contrast with other reports, we found no significant reduction in the pediatric CSF shunt infection rate with the use of AI shunt systems. Any recommendation for or against the routine use of AI systems in children requires a prospective, blinded, randomized-controlled trial with adequate power.

Keywords Shunt infections - Antibiotic-impregnated shunts - Hydrocephalus - Pediatrics

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BMC Infectious Diseases

Research article

A retrospective study of central nervous system shunt infections diagnosed in a university hospital during a 4-year period

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BMC Infectious Diseases 2006, **6**:43 doi:10.1186/1471-2334-6-43

The electronic version of this article is the complete one and can be found online at: http://www.biomedcentral.com/1471-2334/6/43

Received: 9 August 2005
Accepted: 8 March 2006
Published: 8 March 2006

Abstract

Background

Ventriculoperitoneal (VP) shunts are used for intracranial pressure management and temporary cerebrospinal fluid (CSF) drainage. Infection of the central nervous system (CNS) is a major cause of morbidity and mortality in patients with CSF shunts. The aim of the present study was to evaluate the clinical features, pathogens, and outcomes of 22 patients with CSF shunt infections collected over 4 years.

Methods

The patients with shunt insertions were evaluated using; age, sex, etiology of hydrocephalus, shunt infection numbers, biochemical and microbiological parameters, prognosis, clinical infection features and clinical outcome.

Results

The most common causes of the etiology of hydrocephalus in shunt infected patients were congenital hydrocephalus-myelomeningocele (32%) and meningitis (23%). The commonest causative microorganism identified was *Staphylococcus (S.) aureus*, followed by *Acinetobacter spp.*, and *S. epidermidis*.

Conclusion

In a case of a shunt infection the timely usage of appropriate antibiotics, according to the antimicrobial susceptibility testir

BMC Infectious Diseases
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and the removal of the shunt apparatus is essential for successful treatment.

Background

Ventriculoperitoneal shunts are used for maintaining a specific intracranial pressure and generally permanent, but on occasion temporary CSF drainage [1-3]. The placement and revision of VP shunts remains a mainstay in the surgical treatment of hydrocephalus [4]. Infection is the foremost complication of CSF shunt implantation [1,2,4,5]. The incidence CSF infection secondary to ventriculostomy, shunt insertions has been quoted in previous reports as being between 2.2% and 39 % [1,3]. Many factors have been reported to be associated with increased risk of infection, including the age of patient, etiology of hydrocephalus, the type of shunt implanted, and the surgeon's experience [2]. The treatment of shunt infections requires not usually extension of the hospital stay by 2 or 3 weeks and additional surgery [2,6].

The aim of the present study was to evaluate the clinical features, pathogens, and outcomes of 22 patients with cerebrospinal fluid (CSF) shunt infections collected over 4 years.

Methods

The study protocol was approved by the Pamukkale University Research Ethics Committee, Denizli, Turkey, and it complie with the principles outlined in the Helsinki Declaration [7]. Written informed consent was obtained from each patient or a legally designated representative.

The clinical notes of 124 consecutive patients having CNS shunt placement operation for various etiology between 2000 December and 2004 December were reviewed of Pamukkale University, Medical School, Department of Neurosurgery. Operations were performed by two neurosurgeons. One of them (B.C.) has a subspecialty on pediatric neurosurgery. The patients with shunt insertions were analyzed according to; age, sex, etiology of hydrocephalus, shunt infection numbers, prognosis, clinical infection features and clinical outcome. Biochemical and microbiological parameters were evaluated fron the patients' clinical notes and the notes of a specialist in Infectious Diseases.

To define the shunt infected group, at least one of the following criteria was present: 1) the presence of an organism isolated from CSF culture; 2) the presence of fever (>38,5°C) in the absence of other recognized causes, with institution c appropriate antimicrobial treatment and any of the following; increased white cell count (> 50% polymorphonuclear leucocytes), increased protein and/or decreased glucose (< 15 g/dl) in CSF, or organisms visible on CSF Gram stain. While CSF infections within the initial 30 days of ventricular catheter insertion were considered to be early, the infections which occur 30 days after the insertion were considered as late.

Only one dose prophylactic antibiotic (cefuroxime or ampicillin) was given perioperatively to the patients.

Results

Shunt placement operations in 124 patients had been made in the investigation period. Twenty-six (20.9 %) of these 124 patients were younger than two years old. The median age of adult patients were 46 (7–72). The type of the shunt used was a medium pressure type shunt (burr-hole valve medium pressure, from Medtronic, California, USA). Etiological profile CNS shunt placement operations of 124 patients is exhibited in Table 1 Among these 124 patients, 22 (17.7 %) patients were determined as shunt infected. Thirty shunt infection attacks were confirmed in these 22 patients. The group consists 12 males and 10 females. Ten of the 22 patients were younger than two years old. The remaining adult patients' average age was 44.3 years. Clinical data of the 22 patients were designated in Table 2. In our study group, while CSF infections c 14 patients were seen in the early period, infections of remaining 8 patients were seen in the late period. Some of the children had another site infection (urinary tract infection, bronchitis, etc.) and majority of adult patients with comorbiditie had hypertension, diabetes mellitus and another site infection (urinary tract infection, pneumonia). During the study, *Acinetobacter* has been isolated in both CSF and tracheal aspirates simultaneously in two patients. Similarly, *E. coli* in two patients and *Klebsiella pneumoniae* in one patient have been isolated in both urine and CSF. The most common causes of the etiology of hydrocephalus in shunt infected patients were congenital hydrocephalus- closed myelomeningocele (32%) and meningitis (23%); than respectively intracranial mass (23%), intracranial hemorrhage (9%), trauma (9%) and intracranial abscess (4.5%). The intracranial abscess was localized on supratentorial region and the causative microorgani was not identified.

Table 1. Etiological profile of CNS shunt placement operations of 124 patients

Table 2. Clinical data of the patients

From CSF cultures that were taken during each infection attack in only 20 was a microorganism isolated. The most commc causative microorganism identified was *S. aureus*, followed by *Acinetobacter spp.*, and *S. epidermidis* (Table 3).

Table 3. Microbiologic profile of CSF shunt infections attacks

Up to two-thirds of the shunt infected patients' fevers were high (> 38.3°C). From the CSFs that were taken during the 3(infection events, leucocytes counts were increased in 12.

Each infection was treated with external ventriculostomy drainage (EVD) and intravenous antibiotics. The staphylococcus species were susceptible to oxacillin in 7 cases and the 2 patients with a resistant *S. aureus* strain required glycopeptide therapy. Three patients died from complications of shunt infections and 8 patients had a recurrent shunt infection.

Discussion

A variety of different shunt systems have been evaluated but ventriculoatrial (VA) and VP shunts have been employed mo widely in clinical practice [3]. VP shunting has become the diversion procedure of choice because of its shorter operative time and the need for fewer revisions than VA shunts [3]. Although all shunt implant procedures are associated with a higl risk of infection and subsequent mortality [8], the rate of infection does not appear to differ greatly between VA and VP shunts [3].

In our patient' population, the majority of devices were placed for congenital hydrocephalus-myelomeningocele. Many studies suggest that the etiology of hydrocephalus was correlated with infections; however, in our study, the numbers of cases were insufficient to determine this issue [2].

Children are more likely than adults to acquire shunt infection, perhaps because of longer hospital stay, higher skin bacter concentrations, immature immune systems, or more adherent strains of bacteria [9,3]. The rates of infections that are experienced in infants less than 6 months of age are generally two to three times greater than those observed in older children. However, a higher incidence of shunt infections had also been found in the geriatric population [2]. In this study, the shunt infections appeared to be more frequent in the under 2 year-old population.

Early studies reported rates of CSF shunt infection ranging from 1.5 to 39 %; however, during the past two decades infection rates have dropped to 2–9 % [3]. In a recent study in our country the rate of shunt infections was reported to bc 14.5 % [6].

Fever is the most common manifestation of CNS shunt infections. Fever in a patient with CNS shunt should always prompt suspicion of shunt infection. Presentation by other non-specific symptoms such as nausea, vomiting, malaise, headache ar meningismus are variable [2,3,6].

Examination of CSF should be performed in all patients with suspected shunt infection. Bacterial and fungal cultures of CSI in addition to blood culture, should be obtained from these patients. Administration of antibiotics to a patient with suspecte shunt infection before obtaining CSF culture reduces the likelihood of obtaining a positive culture [9].

The bacteria responsible for most shunt infections are commensal organisms with low virulence. As it appears that intraoperative contamination by skin flora or airborne skin organisms are the most important mechanism of infection of CS shunts, efforts have been directed at improving intraoperative asepsis and reducing contamination of the operative field [: The organisms most frequently causing infections of indwelling CNS prostheses are the coagulase-negative staphylococci. The second most frequent pathogen is *S. aureus* [2,3,10,11] Previously published microbiologic profile of CSF shunt infections is showed in Table 4. It should not be forgotten that the cause of nosocomial meningitis and shunt infections are predominantly gram-negative bacilli and microorganisms of the Staphylococcus genus [6,10]. Gram negative enteric bacteria and *Pseudomonas spp.* account for about 5–10 % of infections and are associated with greater morbidity and mortality [3]. In our study, the rate of Gram- negative microorganisms was fairly higher It can be speculated that, simultaneous infections in other parts of the body which were caused by the same gram negative microorganisms may be responsible for that higher incidence. Contrary to the literature, where gram positive microorganisms are found to predominate in the shunt infections, in a recent study reported in our country the results are similar to ours; the rate of

gram negative and positive microorganisms was approximately equal [6].

Table 4. Previously published microbiologic profile of CSF shunt infections[9]

Recent studies in our country report that the most frequent isolated organism of nosocomial meningitis is *Acinetobacter baumannii* [12,13]. Our cases had various predisposing factors for resistant hospital acquired microorganisms such as following treatment in the intensive care unit. Colonization with nosocomial pathogens, broad spectrum antibiotic usage ar serious underlying disease were also contributory factors. Perioperative prophylaxis is generally targeted on staphylococci Host defenses were also impaired, however, because of the foreign body nature of the shunt. In the time period of the isolation of multi-drug resistant *Acinetobacter spp.* from CSF culture there was isolation of the same microorganism from multiple sites in many patients in the intensive care unit.

CSF shunt infections are usually difficult to treat with systemic antibiotics alone [3,8]. In our practice the management of infections associated with CNS shunts was usually surgical removal of the shunt, temporary external CSF drainage, parenteral antimicrobial therapy with shunt replacement after the infection had been eradicated. This approach is the sam as other authors [3,8,14].

Antimicrobials given intrathecally should be constituted in a preservative- free medium to reduce the risk of arachnoiditis. Thus intraventricular antibiotic therapy should be used only if there is a reason to believe that therapeutic CSF concentrations cannot be achieved as a consequence of severe scarring of the choroid plexus or if the antimicrobial of cho is known to have poor CSF penetration, such as an aminoglycoside [3].

The use of perioperative prophylactics for shunt implantation procedures has been controversial [3,14]. Short-term perioperative antimicrobial prophylaxis may be of benefit in preventing shunt infections [3].

Conclusion

Infection remains the most serious complication of VP shunt placement. Although the etiology of shunt infections is predominantly gram positive organisms in many centers, our results show that infections with gram-negative bacteria forr significant species percentage in the shunt infection in our center. We recommend that the catheter should be inserted un aseptic techniques and should not be replaced unless it is clinically demonstrated such as CSF shunt dysfunction etc. In ca of a catheter infection, it is both necessary to remove the shunt and commence the systemic antibiotic treatment. It shoul also not be forgotten that the timely usage of appropriate antibiotics according to the antimicrobial susceptibility testing is essential for successful treatment.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

SS carried out the microbiological studies, conceived of the study, and participated in its design and coordination. HT and participated in the design of the study and wrote the manuscript. ST, BC, EC, OY participated in the collection and clinical evaluation of patients. All authors read and approved the final manuscript.

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Pre-publication history

The pre-publication history for this paper can be accessed here:

http://www.biomedcentral.com/1471-2334/6/43/prepub

A Registry for Comparing Catheter-Related Infection Rates Among Various Shunt Systems in the Treatment of Hydrocephalus

This study is currently recruiting participants.
Information provided by Codman & Shurtleff

This Tabular View shows the required WHO registration data elements as marked by †

Descriptive Information Fields

Brief Title †
A Registry for Comparing Catheter-Related Infection Rates Among Various Shunt Systems in the Treatment of Hydrocephalus

Official Title †
A Registry for Comparing Catheter-Related Infection Rates Among Various Shunt Systems in the Treatment of Hydrocephalus

Brief Summary
The purpose of this Registry is to compare shunt/catheter-related infection rates among various shunt systems when used according to hospital standard of care to treat hydrocephalus.

Detailed Description
Clinical trials show that the majority of infections in shunt systems originate from bacterial contamination introduced at the time of surgery and most appear by 3-4 weeks post-operatively. Protection must persist well beyond the surgical procedure to make certain that all contaminating bacteria are completely eradicated.

Depending upon the institution, shunt infection rates have been known to be as little as 1% to as much as 25%. However, two prospective trials that have been published from large databases, with a consistent definition of infection, have indicated an overall infection rate of approximately 10%

This prospective non-randomized, open-label Registry is designed to investigate and identify short-term shunt/catheter-related infection rates in ventriculoperitoneal shunt systems using various catheters during hospital standard of care treatment of Subjects with hydrocephalus. Prospective Subjects will include those receiving shunts for the first time (de novo) and those with previously implanted shunts for whom catheter or total system replacements are required.

This Registry will enroll 450 implanted Subjects of any age who meet all the inclusion criteria and none of the exclusion criteria and who provide signed Informed Consent to participate in this clinical Registry

Subjects will be followed for up to 90 days.

Study Phase
Phase IV

Study Type †
Observational

Study Design †
Cohort, Prospective

Primary Outcome
The primary outcome for this Registry is shunt/catheter-related infection within the context of treatment using a ventriculoperitoneal shunt system [Time Frame: End of trial] [Designated as safety issue: Yes]

Measure †	
Secondary Outcome Measure †	Non-Infectious Catheter Failure [Time Frame: End of trial] [Designated as safety issue: No] Catheter/shunt Obstruction [Time Frame: End of trial] [Designated as safety issue: No]
Condition †	Hydrocephalus
Intervention †	Device: Shunt catheter
MEDLINE PMIDs	
Links	

Recruitment Information Fields

Recruitment Status †	Recruiting
Enrollment †	450
Start Date †	January 2006
Completion Date	March 2008
Eligibility Criteria †	Inclusion Criteria:

- The Subject requires a surgical procedure to implant (de novo) a ventriculoperitoneal shunt or to replace an already implanted shunt catheter for the treatment of hydrocephalus.
- The Subject (family member/legal representative) has completed the Informed Consent process prior to enrollment into this Registry.
- The Subject (family member/legal representative) is willing to comply with the Registry protocol timelines & requirements.

Exclusion Criteria:

- The Subject's planned shunt has distal drainage to the heart.
- The Subject has an active infection of the indwelling shunt system, cerebrospinal fluid or abdominal cavity.
- The Subject has ventriculitis, peritonitis or meningitis.
- The Subject has sepsis.
- The Subject has a history of poor wound healing.
- The Subject has symptoms pertaining to: a skin infection at or near the site of any incisions; an ear infection on either side; a respiratory tract infection; or a urinary tract infection that, in the Investigator's opinion is clinically significant and might compromise the outcome of this Registry.
- The Subject has had any form of bowel surgery 30 days prior to device implant or anticipates bowel surgery within 90 days following device implant
- The Subject has loculation(s) within the ventricular system.
- The Subject is otherwise determined by the Investigator to be medically unsuitable for participation in this Registry.
- The Subject is currently enrolled in another drug or device trial or has been previously entered in this trial.

- The Subject exhibits other difficulties, which would preclude follow-up for 90 days.
- The Subject is a prisoner.

Gender	Both
Ages	
Accepts Healthy Volunteers	No
Contacts ††	Contact: Irene Cheng (508)828-3079 icheng@dpyus.jnj.com
Location Countries †	United States, Canada, China, Hong Kong, India, Singapore

Administrative Information Fields

NCT ID †	NCT00280904
Organization ID	CRI-IN04-001
Secondary IDs ††	
Study Sponsor †	Codman & Shurtleff
Collaborators ††	
Investigators †	Study Chair: Paul Steinbok, MBBS, FRCSC University of British Columbia
Information Provided By	Codman & Shurtleff
Verification Date	January 2008
First Received Date †	January 20, 2006
Last Updated Date	January 11, 2008

† **Required WHO trial registration data element.**

†† **WHO trial registration data element that is required only if it exists.**